510(k) Summary

Submitter:	Edwards Lifesciences LLC
Contact Person:	Luke Meidell, Regulatory Affairs Associate II 12050 Lone Peak Pkwy Draper, UT 84020 Ph - (801) 565-6212 Fax – (801) 565-6108
Date Prepared:	March 06, 2014
Trade Name:	Edwards Catheter Introducer Sheath
Classification Name:	Introducer, Catheter, Cardiovascular Devices Panel; 21 CFR §870.1340 Product Code DYB, Class II
Predicate Device:	K981909, Baxter Hemostasis Valve Introducer

Device Description:

Edwards Lifesciences' Catheter Introducer Sheath is an 11 Fr. sterile, non-pyrogenic, single-use introducer made of flexible and non-flexible polymeric materials. It consists of a single lumen shaft and a hemostasis valve with a side-arm extension tube with a female luer and clamp.

Intended Use:

Intended to be used to access the venous system and to facilitate catheter insertion and allow access for the administration of fluids and blood sampling.

Indications for Use:

The Catheter Introducer Sheath is indicated for use in patients requiring access of the venous system or to facilitate catheter insertion (e.g. pulmonary artery or infusion catheter). It is intended to be used for ≤ 72 hours.

Comparative Analysis:

The subject device has the same intended use and technological characteristics (i.e., design, material, chemical composition) as the predicate device. It has been demonstrated that the subject Catheter Introducer Sheath is comparable to the predicate

device in fundamental scientific technology, material types, principles of operation, and functional performance evaluations. No new issues of safety or efficacy have been raised as a result of the packaging configuration change or the revision of the Indications for Use statement.

Functional/Safety Testing:

The functional data indicate that the Catheter Introducer Sheath performs in a substantially equivalent manner when compared to the predicate device. The following tests were performed:

Biocompatibility and Sterility

Cytotoxicity, Sensitization, Irritation/Intracutaneous toxicity, Systemic toxicity, Genotoxicity, Haemocompatibility, Muscular toxicity, Subacute/Subchronic toxicity, *In Vivo* thrombogenicity,

Performance / Shelf Life

- **Leak Testing**

  Valve Leak after 72-hour insertion of 7 Fr device, Assembly leak, Valve leak after 6-hour insertion of 9 Fr device, Valve leak after 6-hour insertion of 7 Fr device, Valve leak with no insertion conditioning, Valve leak after multiple insertions, Forward valve leak.

- **Tensile Testing**

  Introducer joint tensile, Sideport luer tensile, Sideport tubing to body.

- **Compatibility and Additional Testing**

  9 Fr ballon catheter insertion force, 9 Fr balloon catheter retraction force, Dilator insertion force, Contamination guard connection, Introducer sheath and dilator transition, Valve retention force, Sideport infusion with empty introducer, Sideport infusion post clamping, Sideport infusion with 10 Fr device, Fluoroscopic visibility, Kink testing.

Packaging Testing

All data met acceptance criteria.

Conclusion:

The Edwards Catheter Introducer Sheath is substantially equivalent to the cited predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 6, 2014

Edwards Lifesciences, LLC.
% Luke Meidell
Regulatory Affairs Associate III
12050 Lone Peak Pkwy
Draper, UT 84020 US

Re: K131627
Trade/Device Name: Catheter Introducer Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: February 12, 2014
Received: February 14, 2014

Dear Mr. Meidell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K131627

Device Name: Catheter Introducer Sheath

Indications for Use:

The Catheter Introducer Sheath is indicated for use in patients requiring access of the venous system or to facilitate catheter insertion (e.g. pulmonary artery or infusion catheter). It is intended to be used for ≤ 72 hours.

Prescription Use ___x___ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office Of Device Evaluation (ODE)